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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,212	12/19/2005	Toyoaki Ishikura	40072-0028	2250

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

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04/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,212	ISHIKURA ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/19/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

For reference #A02, cited in the IDS of 19 December 2005, the Derwent English Abstract was considered. Note that an English translation of the entire document was not provided.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the priority document, Japan 2003-175646 has been filed in the instant Application filed on 12/19/2005.

Claim Objections

Claims 5, 8-9 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5, 8 and 14 are seen recite dependencies from two parent claims. Claim 9 is drawn to the coprecipitate of claim 1 and further recites an intended use, which is not seen to further limit the parent claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a coprecipitate of 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine and hydroxypropylmethyl cellulose and methyl cellulose and a process for making the same, does not reasonably provide enablement for a coprecipitate of 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine and all other water soluble polymers and the process for making them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught

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one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of one of ordinary skill
- (D) The level of predictability in the art
- (E) The amount of direction provided by the inventor
- (F) The existence of working examples
- (G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 1 and 11 are drawn to a coprecipitate of 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine and a water soluble polymer and a process for making the said coprecipitate. The terms, a water soluble polymer, is broad and is seen to encompass any polymer that is water soluble including ones that are unknown at the time of filing of the instant claims. Water soluble polymers are also structurally diverse. Also, the term water soluble does not specify the extent of solubility in water.

The state of the prior art

The examiner notes that prior art Ohtsuka (US 6,372,735) and Butler (US 5,985,326), and also used in the rejections below, disclose and exemplify cellulosic polymers for making coprecipitates as instantly claimed. However these compounds are structurally different from all the other water soluble polymers and are not correlative for the broadly claimed water soluble polymers and the process in the instant claims.

The level of predictability in the art

There is not seen sufficient data in the prior art cited to substantiate the use of any water soluble polymer to obtain a coprecipitate with benzazepine as instantly claimed. Coprecipitation also depends on the extent of solubility of the polymer in water, depending on the temperature and is different for different polymers. Coprecipitation is also dependent on the interaction between the polymer and the instant benzazepine. Not all polymers will be compatible or interact in a manner with the claimed benzazepine to cause coprecipitation.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the formation of the coprecipitate of the benzazepine with any water soluble polymer. The specification provides reference to Simonelli et al's disclosure (page 3, paragraph 0008) regarding the coprecipitates of sulfathiazole and polyvinylpyrrolidone via a thermal melting method and its failure when applied to the instant compound. This points out to the fact that the use of any polymer and the method of making is not correlative.

The existence of working examples

The working examples set forth in the instant specification are drawn to coprecipitates of the instant benzazepine using methyl cellulose and hydroxypropyl cellulose as the water soluble polymers and the process of making these. Despite these examples there is little enabling disclosure for the same using other types of water soluble

polymers and is therefore not entitled to claim using any water soluble polymer other than cellulosic polymers.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the coprecipitate of the instant benzazepine with any water soluble polymer and the process for making the same. One of ordinary skill in the art would have to carry out the process in order to determine which among the myriad water soluble polymers to use in the process and other process conditions such as ratios, temperature, etc. in order to make the coprecipitate. Undue experimentation is needed to make the coprecipitate via the process as instantly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4 recite the limitation "specific diffraction angles and exothermic and endothermic peaks" in claim 1. There is insufficient antecedent basis for this limitation in the claim. The diffraction angles and the exothermic and endothermic peaks recited in claims 3-4 are specific for the coprecipitate claimed and obtained by the instant method and the specific

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cellulosic polymer used (hydroxypropylmethyl cellulose and methyl cellulose) as seen in the instant examples. Parent claim 1 recites the broad terms, "a water soluble polymer". This is seen to include every water soluble polymer in addition to hydroxypropylmethyl cellulose and methyl cellulose. The same specific diffraction angles in X-ray diffraction pattern and peaks in differential scanning calorimetry cannot be obtained if the coprecipitate is obtained by a different method. Instant claim 1 does not recite how the said coprecipitate is obtained in addition to the polymer claimed being broad.

Claims 13-14 provide for the use of the coprecipitate of parent claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 7,229,985 ('985). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant Claim 1 is drawn to a coprecipitate of 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine and a water soluble polymer. Claims 2-15 are drawn to characteristics in diffraction pattern, DSC, solubility of the active agent, ratio of the benzazepine to polymer, the type of water soluble polymer, specific cellulosic polymers, process for making the coprecipitate and the use of the coprecipitate in making an antiallergic medication and method treatment and prevention of allergic disease. Claim 1 of '985 is drawn to a composition comprising the same benzazepine derivative in methylcellulose and hydroxypropylcellulose. Claims 4-5 are drawn to a process for making the said composition using a lower alcohol and methylene chloride as a water soluble medium. Claims 6-13 are drawn to pharmaceutical composition and method of treatment of allergic disease.

Claims 1-13 of '985 differ from the instant claims in that the instant claims employ a water soluble organic solvent in addition to a water soluble lower alcohol in the process for making the said composition. One of skill in the art knows that a lower alcohol also has water in it. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the active agents and the polymers could be successfully employed in the composition, pharmaceutical composition, and method of '985.

In determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). In the instant case, '985 teaches performing each of the steps applicant claims using the same active agent and the water soluble polymers. Although the claims of '985 employ an additional water immiscible solvent, one of ordinary skill in the art would readily recognize that the scheme taught by '985 could be employed for making the composition via the process as instantly claimed even without employing the water immiscible organic solvent. The use of known members of classes of agents in compositions and reactions to effectuate the same type of modifications taught in the prior art is not seen to render the instantly claimed compositions and methods unobvious over the art. Once the active agents/ingredients and the general reaction has been shown to be old, the burden is on the applicant to present reason or authority for believing that the use of a slightly different would take part in or affect the basic reaction and thus alter the nature of the product or the operability of the process and thus the unobviousness of the method of producing and using it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohtsukha et al (US 6,372,735).

Ohtsuka et al teach triazolobenzazepine derivatives, one of which is the same as the instantly claimed 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine (col. 2, line 5 through col. 5, line 20 and col. 11, lines 7-11). Examples 1-2 (col. 54) teach a coprecipitate of compound 20 (see table 2; compound 20 is the same as the benzazepine instantly claimed) with hydroxypropyl cellulose (water soluble polymer). This teaching reads on instant claims 1, 6-7 and 9. The coprecipitate of Ohtsukha also contains lactose (a pharmaceutically acceptable carrier; limitation of instant claim 8).

The compound is useful as a therapeutic agent for treatment and prevention of allergic diseases (col. 22, lines 11-16). The compound can be formulated using excipients like cellulose as a binder (col. 22, lines 17-22) in to a tablet (col. 54, Examples 1-2; limitations of instant claims 8-10 and 13-14). Ohtsuka et al teach the use of the compositions of compound 20 with hydroxypropyl cellulose and methylcellulose for in a method for treatment of allergic diseases (col. 58, lines 54-63; limitations of instant claim 15).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtsukha et al (US 6,372,735) in view of Butler (US 5,985,326).

Ohtsukha's teaching is as discussed above. In addition to the above Ohtsukha teaches the required dosage and also suggests increasing or decreasing the dosage depending on the intended

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use (col. 22, lines 40-55). Depending on the preparation Ohtsukha also suggests a range for the the instant active compound (col. 22, 35-55).

Butler drawn to coprecipitation of drugs, teaches a process for the same wherein drugs (heterocyclic drugs similar to the instant benzazepine, col. 1, lines 19-28) is mixed with an non-aqueous (i.e. organic) water miscible solvent, a carrier and water to obtain the coprecipitate (col. 2, lines 41-56; col. 9, lines 11-60). The carrier is hydroxypropylmethyl cellulose. According to Butler coprecipitation method is used to increase the solubility of poorly soluble drugs (col. 1, lines 19-28).

However, both Ohtsukha and Butler do not teach the extent of solubility and the ratio of the drug and the polymer as instantly claimed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a coprecipitate of the benzazepine and a water soluble cellulosic polymer in the ratio and solubility range as instantly claimed since the coprecipitate is used in different forms of administration and the ratios and amounts could be varied depending on the use as taught by Ohtsukha.

One of skill in the art would be motivated to make the coprecipitate using the ratio of the benzazepine to polymer and having the solubility as instantly claimed in order to optimize the solubility of the active agent so that maximum beneficial effect can be achieved. It is well within the skill level of the artisan to adjust the solubility and the ratios of the ingredients based on the teachings of the prior art.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtsuka et al (US 6,372,735) in view of Butler (US 5,985,326).

Ohtsuka et al teach triazolobenzazepine derivatives, one of which is the same as the instantly claimed 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H), 10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzazepine (col. 2, line 5 through col. 5, line 20 and col. 11, lines 7-11). The compound is useful as a therapeutic agent for allergic diseases (col. 22, lines 11-16). The compound can be formulated using cellulose and hydroxypropyl cellulose (col. 22, lines 17-22). Table 2 shows the formula of compound 20, which is the compound instantly claimed. However, Ohtsukha does not teach a method of making the composition of his invention using the process steps as instantly claimed (col. 54, Examples 1-2). In the process of Ohtsukha the ingredients are intimately mixed with water and dried to get the composition. An organic solvent is not used. Several water miscible organic solvents can be used including the ones recited in instant claim 12 (col. 4, lines 41-45).

Butler drawn to coprecipitation of drugs, teaches a process for the same wherein drugs (heterocyclic drugs similar to the instant benzazepine, col. 1, lines 19-28) is mixed with a non-aqueous (i.e. organic) water miscible solvent, a carrier and water to obtain the coprecipitate (col. 2, lines 41-56; col. 9, lines 11-60). The carrier is hydroxypropylmethyl cellulose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a coprecipitate of the benzazepine and a water soluble cellulosic polymer via a process as instantly claimed since the process steps for making analogous precipitates, which are same as the steps instantly claimed, is taught in the prior art using the same water soluble polymers, water and water miscible organic solvents.

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One of skill in the art would be motivated to use the process as instantly claimed (and taught by the prior art) since the process steps are simple and are recognized (by Butler; col. 1, lines 19-25) to be applicable to structurally diverse type of heterocyclic drugs similar to the one instantly claimed. One of skill in the art would also prefer to use cellulosic polymers since Ohtsuka et al disclose toxicity tests for compositions of compound 20 (instant compound) with hydroxypropyl cellulose and methylcellulose that show that these polymers are (col. 54, line 3 through col. 55, line 18) safe even at a dosage of 2g/Kg.

Conclusion

Claims 1-15 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623